

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

Claim 1-50 (canceled)

5 Claim 51. (currently amended): A powdery composition for nasal administration comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii) one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α -cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

51
Cont'd

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is obtained by a method comprising [[strongly]] mechanically mixing the drug with the water-absorbing and water-insoluble base material to obtain a resultant mixture, in which at least 90 wt % based on the water-absorbing and water-insoluble particles have an average particle diameter in the range of 10-350 μm , using a universal mixer, a ribbon mixer, an automatic mortar, a ball mill, a high-speed mixer or a powerful automatic mixer, and

subsequently, mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt % based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm , with the resultant mixture.

Claim 52. (previously presented): A powdery composition for nasal administration comprising

- (i) a drug,
- (ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and
- (iii) one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α -cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is obtained by a method comprising adhering the drug to the water-absorbing and water-insoluble base material by freeze drying,

then, pulverizing and sieving the water-absorbing and water-insoluble base material with the adhered drug to obtain a resultant water-absorbing and water-insoluble base material comprising water-absorbing and water-insoluble particles, wherein at least 90 wt % based on the resultant water-absorbing and water-insoluble particles have an average particle diameter in the range of 10-350 μm , and

subsequently, mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt % based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm , with the resultant water-absorbing and water-insoluble base material.

Claim 53. (previously presented): A powdery composition for nasal administration comprising

(i) a drug,

(ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and

(iii) one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α -cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,

wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is obtained by a method comprising dissolving or dispersing the drug and the water-absorbing and water-insoluble base material in an organic solvent to obtain a resultant solution or dispersion, and

subsequently evaporating the resultant solution or dispersion to obtain a powder,

51
cont'd
further pulverizing and sieving the powder to obtain a resultant powder comprising water-absorbing and water-insoluble particles, wherein at least 90 wt% based on the water-absorbing and water-insoluble particles have an average particle diameter in the range of 10-350 μm , and

mechanically mixing the water-absorbing and gel-forming base material, in which at least 90 wt% based on the water-absorbing and gel-forming particles have an average particle diameter in the range of 10-350 μm , with the resultant powder.

Claim 54. (previously presented): A powdery composition for nasal administration comprising

- (i) a drug,
 - (ii) one or more of a water-absorbing and gel-forming base material selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, hydroxyethyl cellulose, and sodium carboxymethyl cellulose and
 - (iii) one or more of a water-absorbing and water-insoluble base material selected from the group consisting of crystalline cellulose, α -cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, chitin and chitosan,
- wherein the content of the water-absorbing and gel-forming base material is about 5-40 wt% based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material,

70 wt % or more based on the drug is dispersed on or in the water-absorbing and water-insoluble base material and on or in the water-absorbing and gel-forming base material,

the water-absorbing and water-insoluble base material and water-absorbing and gel-forming base material comprise particles,

wherein the drug is dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material, and

wherein the powdery composition is obtained by a method comprising making an average particle diameter of the water-absorbing and water-insoluble base material larger than an average particle diameter of the water-absorbing and gel-forming base material.

Claim 55. (previously presented): A powdery composition for nasal administration according to claim 54, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-350 μm in at least 90 wt % based on the water-absorbing and water-insoluble particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-105 μm in at least 90 wt % based on the water-absorbing and gel-forming particles.

Claim 56. (previously amended): A powdery composition for nasal administration according to claim 54, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-250 μm in at least 90 wt % based

on the water-absorbing and water-insoluble particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-65 μm in at least 90 wt % based on the water-absorbing and gel forming particles.

51
Amended

Claim 57. (previously presented): A powdery composition for nasal administration according to any one of Claims 51-56, wherein the drug is selected from the group consisting of non-peptide/non-proteinaceous drugs and peptide/proteinaceous drugs having molecular weight of 30,000 or less.

Claim 58. (previously presented): A powdery composition for nasal administration according to Claim 57, wherein the non-peptide/non-proteinaceous drug is one or more drugs selected from the group consisting of anti-inflammatory steroids, nonsteroidal anti-inflammatory drugs, analgesic anti-inflammatory agents, antitussive expectorants, antihistaminic agents, antiallergic drugs, antiemetic drugs, hypnotics, vitamin preparations, sex steroid hormones, antineoplastic drugs, antiarrhythmic drugs, antihypertensive drugs, antianxiety drugs, psychotropic drugs, antiulcer drugs, cardiotonics, analgesics, bronchodilators, treating agents for obesity, antithrombotic drugs, antidiabetic drugs, muscle relaxants and anti-rheumatics.

Claim 59. (currently amended): A powdery composition for nasal administration according to Claim 57, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of luteinizing hormone-releasing hormones, growth hormone-releasing factors, ~~somatostatin analogs~~ somatostatins,

51
central
vasopressins, oxytocins, ~~hirudin analogs~~ hirudins, enkephalins, adrenocorticotrophic
~~hormone analogs~~ hormones, ~~bradykinin analogs~~ bradykinins, calcitonins, insulins,
~~glucagon analogs~~ glucagons, growth hormones, growth hormone-releasing hormones,
luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides,
~~atrial natriuretic polypeptide analogs~~ atrial natriuretic polypeptides, interferons,
erythropoietin, granulocyte colony forming-stimulating factor, macrophage forming-
stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone,
prolactin, thyroid-stimulating hormone-releasing hormone and angiotensins.

Claim 60. (previously presented): A powdery composition for nasal administration according to any one of Claims 51-56, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 500-1500, and the amount of the water-absorbing and gel-forming base material is about 5-30 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material.


Claim 61. (currently amended): A powdery composition for nasal administration according to Claim 60, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of vasopressins, luteinizing hormone-releasing hormones, growth hormone-releasing factors, ~~somatostatin analogs~~ somatostatins, oxytocins, ~~hirudin analogs~~ hirudins, enkephalins, adrenocorticotrophic ~~hormone analogs~~ hormones and ~~bradykinin analogs~~ bradykinins.

51
Cmty

Claim 62. (previously presented): A powdery composition for nasal administration according to any one of Claims 51-56, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 1500-30,000 and the amount of the water-absorbing and gel-forming base material is about 5-20 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material.

Claim 63. (currently amended): A powdery composition for nasal administration according to Claim 62, wherein the peptide/proteinaceous drug is one or more drugs selected from the group consisting of calcitonins, insulins, ~~glucagon~~ analogs glucagons, growth hormones, growth hormone-releasing hormones, luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides, atrial natriuretic ~~polypeptide analogs~~ polypeptides, interferons, erythropoietin, granulocyte colony-stimulating factor, macrophage-stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone, prolactin, thyroid-stimulating hormone-releasing hormone and angiotensins.

Claim 64. (previously presented): A powdery composition for nasal administration according to any one of Claims 51-56, wherein the water-absorbing and water-insoluble base material is crystalline cellulose.

 Claim 65. (previous presented): A powdery composition for nasal administration according to any one of Claims 51-56, wherein the water-absorbing and gel-forming base material is hydroxypropyl cellulose.

Claim 66. (previous presented): A powdery composition for nasal administration according to Claim 65, wherein the hydroxypropyl cellulose has a viscosity of 150-4000 cps in 2% aqueous solution.

Claims 67-98 (canceled)
